

## REMARKS

Claims 2 and 7 have been cancelled. The claims now present in this application are claims 1, 3-6 and 8-41. This Amendment supplements the prior Amendment submitted on January 16, 2009.

The prior Amendment submitted on January 16, 2009 was for submitting an application data sheet and to recite in the specification of the instant application information of the priority application and to set forth that the instant application was an National Phase Application filed under 35 U.S. 371 of the PCT Application, PCT/CH2004/006655 filed on October 25, 2004.. In view of the prior Amendment , it is submitted that the claim to priority has been effectuated and this issue and the issues raised with respect to priority on pages 2-4 of the Office Action and the oath/declaration on page 5 of the Instant Office Action have been have been obviated.

In this Amendment, claims 1 and 41 have been amended to change the term "if desired" to -- optionally. Claims 11 through 13, 16, 20, 24, 25, 27 and 31 have been amended to recite proper Markush language, said language being "selected from the group consisting of" In claim 41 the word "of" has been inserted between the "mixture" and "sodium naproxen" In view of these amendments the objections to the claims set forth on page 5 of the aforementioned Office Action have been complied with.

Claim 1 has been amended to insert the limitations of claims 2 and 7. In accordance with this amendment it is clear that the basic auxiliary agent component in claim 1 comprises one or more basic agents which basic agents contained in said component must constitute at least 5% by weight based upon the weight of the tablet core. The claim also sets forth that the basic auxiliary agent component is present in

the amount of from 5% to 70% based upon the weight of the tablet core. All weight percentages in the claims are based upon the weight of the tablet core. In this manner if the auxiliary agent component is 5 %of the tablet core it must entirely be consist of the basic auxiliary agent. As seen from claims 14-23, the auxiliary agent component can contain other ingredients besides the basic auxiliary agents. This is in accordance with the disclosure on page 5 lines 5-8 of the instant specification. Please note that in this passage ,the “auxiliary agent component” is singular and “one or more basic auxiliary agents” is plural. Hence “their” in the statement that “their totaled amount is preferably at least 5 %” is plural and must refer to the agents and not to the component.

All of the claims have been rejected has unpatentable over Kuramoto in view of Panoz this rejection is respectfully traversed.

The claimed invention is directed to a non-effervescent tablet for oral administration. This tablet comprising a tablet core of sodium naproxen and auxiliary agent component which comprises at least one basic auxiliary agent where the agent constitutes at least 5% by weight of the tablet core. On page 10 of the Office Action it is correctly noted that the difference between the teaching of Kuramoto and the claimed tablet of this invention is the addition of a basic auxiliary agent to the tablet. Panoz is cited for teaching the addition of a basic auxiliary agent. Contrary to this assertion Panoz et al. does not teach adding a basic auxiliary agent in formulating a sodium naproxen tablet. If anything Panoz teaches away from the use of basic auxiliary agent such claimed herein in formulating such sodium naproxen tablets.

It is correct that Panoz, in column 3, lines 2-8 and column 5, lines 57-64, teaches the use of both alkaline and acidic pH adjusting compounds to adjust the pH to of the particular medicament to an alkaline or acid pH. However Panoz teaches

that whether an alkaline or acidic pH adjusting compounds is used depends upon the particular medicament. Panoz specifically teaches that for weakly alkaline active ingredient the pH is adjusted using an acidic pH adjuster. Please note that sodium that sodium naproxen is an example of a weakly alkaline active ingredient. In this case the pH according to Panoz should be adjusted using an acidic pH adjuster and not by the use of one or more basic auxiliary agents. Panoz also sets forth that for active ingredients being unstable in acidic media, the pH adjusting compound should be a base. Please note column 5, lines 18-22 and claim 2 of the Panoz reference. A sodium naproxen formulating in accordance with the instant invention is neither weakly acidic nor unstable in a acidic media. Accordingly, Panoz teaching to use for the free naproxen acid, not for sodium naproxen a basic pH adjuster as set forth in column 5 lines 41-50.

The teaching of Panoz to use acid adjusting agents for weakly not bases is further emphasized in Panoz by the examples which show that for that weakly acidic active principles the acidic pH adjusting agent used is also an acid. Please note the examples as follows:

Example No.	acidic pH adjusting agent	weakly acidic active principle
1	citric acid	quinidine sulphate (= quinidine sulfuric acid addition salt)
2	fumaric acid	quinidine sulphate
9	fumaric acid	propranolol HCl (= propranolol hydrochloric acid addition salt)
10	fumaric acid	diltiazem HCl (= diltiazem hydrochloric acid addition salt)

In none of these examples does Panoz alkali or basic adjusting agents with a weakly alkaline active ingredient. Such as sodium naproxen. . Furthermore Panoz only teaches as exemplary basic active principles, neutral ones or inner salts, but not

anionic ones. See column 5, lines 27-37, claim 4 of Panoz. The sodium naproxen of the instant invention is an anionic basic active principle. Panoz mentioning of quinidine sulphate as a weakly alkaline active principle is erroneous, it is weakly acidic (see table above).

On of the benefits of the claimed sodium naproxen tablet formulation of o the instant invention is its ability to dissolve quickly in gastric juice. See the instant application page 9, lines 6-13. Panoz carried out the dissolution kinetics in an acidic media of pH 1.5, and studied only one formulation in example 11 containing a basic pH adjusting agent which . Panoz designates as. sodium citrate. . See column 13, lines 3-6of Panoz. Panoz found that the dissolution of indomethacin at pH 1.5 was slowed down by the presence of the sodium citrate (see column 11, lines 21-34 and curves c and d in figure 17). Clearly Panoz teaches away from adding basic auxiliary to increase the dissolution of an active agent in acidic media. Such increase is however observed in the instant application for sodium naproxen, once the amount of basic auxiliary is at least 5% by weight. Please note in the instant application page 29, lines 21-27 and figure 2).

In summary that Panoz clearly teaches away from using a basic pH adjusting compound together with the basic anionic active principle sodium naproxen of the instant invention. Independent claims 1 and 41, and therefore claims 2-40 depending from claim 1, are thus inventive over the combination Kuramoto/Panoz. combination

The Patel reference US 2003/0180352 cited as a ternary reference against claims 30-32 does not add anything to the combination of. Kuramoto and Panoz. Claims 30-32 are claims depending from claim 1 and are therefore inventive over Kuramoto/Panoz (see above). While the further Patel reference may teach the addition of surfactants to formulations, it does not address above discussed

deficiencies of Kuramoto/Panoz vs. claims 1 and 41, namely teaching away from the combined use of basic auxiliary agent together with a weakly basic active agent and teaching away from increasing the dissolution rate in acidic media using the basic auxiliary. Independent claims 1 and 41, and thus claims 2-40 depending from claim 1, are inventive even over Kuramoto/Panoz/Patel combined.

Furthermore, specifically as to claims 30-32, Applicant notes that Patel hints at that by using the surfactant the amount of basic auxiliary may be reduced or even completely dispensed with (paragraphs 256 and 19/20). This would further teach away from using at least 5% basic auxiliary agent together with a tenside, as required by claims 30-32 in combination with now suggested claim 1.

Based upon the foregoing, it is submitted that all of the claims as now presented in this Application are in condition for allowance. A prompt Notice of Allowance is respectfully requested.

### ***Correspondence and Fees***

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account no. 03-3839 for any underpayment, or to credit any overpayments.

Please address all correspondence to the correspondent address for Customer No. 26345 of Intellectual Docket Administrator, Gibbons P.C., One Gateway Center, Newark, NJ 07102-5310. Telephone calls should be made to William H. Epstein at (973) 596-4607 and fax communications should be send directly to him at (973) 639-6397.

Respectfully submitted,

/William H. Epstein/

William H. Epstein  
Attorney for Applicant(s)  
Registration No. 20,008

Gibbons P.C.  
One Gateway Center  
Newark, NJ 07102